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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ALAN P. WOLFFE and FYODOR URNOV

Appeal 2008-0404
Application 10/083,682
Technology Center 1600

Decided: September 15, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES,
Administrative Patent Judges.

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 66-71 and 125-128 are on appeal. Claims 66 and 67 are representative of the appealed subject matter and read as follows:

66. A polynucleotide, wherein the polynucleotide is a member of a library of polynucleotides, the members of the library comprising a vector and an insert, wherein the insert sequences consist essentially of accessible regions of cellular chromatin, wherein the library is obtained according to the method of:

(a) contacting cellular chromatin with a probe, wherein reaction of the probe with cellular chromatin results in polynucleotide cleavage at accessible regions of cellular chromatin;

(b) deproteinizing the cleaved chromatin of step (a);

(c) digesting the deproteinized chromatin of step (b) with a nuclease to generate a collection of polynucleotide fragments; and

(d) selectively cloning polynucleotide fragments comprising one end generated by probe cleavage.

67. A library comprising a plurality of polynucleotides according to claim 66.

Cited Reference

Clontech Catalog, (1998-1999) Clontech Laboratories, Inc. 177-183.

Grounds of Rejection

Claims 66-71 and 125-128 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Clontech.

DISCUSSION

Background

“The present disclosure relates to the fields of bioinformatics, gene regulation, gene regulatory sequences, gene regulatory proteins and methods of determining gene regulatory pathways.” (Spec. 1.)

Claims 66-71 and 125-128 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Clontech. We select claims 66 and 67 as representative of the rejection before us since Appellants have not separately argued individual claims in the Brief or Reply Brief. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner finds that:

Clontech Catalog discloses multiple genomic libraries made from cellular chromatin of different organisms using different vector systems. See pages 177-183, especially the table on pages 182-183. These genomic libraries are made by a method involving digesting genomic DNA, which is from cellular chromatin, of the different organisms with restriction enzymes, Sau3AI and MboI, which are four cutters and are known in the art to digest the genomes with high frequency, and cloning the digested fragments in different vector systems. See page 177. Given that Sau3AI and MboI are restriction enzymes having recognition sites that occur frequently in the genome, it would be readily apparent to one of skill in the art that the libraries produced by such a method inherently comprise clones that either have an insert that consists entirely of polynucleotide sequence from regions of cellular chromatin that are accessible to reagents such as nuclease and restriction enzymes, as recited in claims 125-128, or have an insert that comprises polynucleotide sequence from the accessible region and sequence from the inaccessible region in the same insert.

(Ans. 4-5.)¹

¹ Reference to the Answer throughout is to the Answer dated May 8, 2007.

The Examiner further finds that:

Due to the use of transitional phrase “consisting essentially of” in claim 66, it is interpreted that the claimed polynucleotide, i.e. the insert, can include sequence from accessible region and sequence other than the accessible region. Thus, the libraries disclosed by Clontech and certain clones contained therein are the same as the polynucleotides or library thereof in the instant product-by-process claims.

(Ans. 5.) The Examiner further argues that the term “consisting essentially of” is not defined in the Specification and thus should be construed as equivalent to the term “comprising.” (*Id.* at 7.)

Appellants contend that the Examiner has misinterpreted the phrase “consisting essentially of” in claim 66 to include “polynucleotides corresponding to inaccessible regions.” (App. Br. 13.)² Appellants argue that “the basic and novel characteristics of the claimed polynucleotides and libraries are that they arise from, and correspond to, accessible regions of cellular chromatin.” (*Id.* at 13.)

Appellants further argue that:

because the claimed libraries are made from cleaving cellular chromatin (in which inaccessible regions are protected from cleavage by associated proteins), the inserts in the library of the claims will never include only inaccessible regions and, moreover if any sequences corresponding to inaccessible regions are present in these inserts, they will be immaterial.

(Reply Br. 3.)³

² Reference to the Appeal Brief throughout is to the Appeal Brief dated December 26, 2006.

³ Reference to the Reply Brief throughout is to the Reply Brief dated July 9, 2007, unless otherwise stated.

We find that when the Specification is viewed as a whole it discloses that the basic and novel characteristics of the claimed polynucleotides and libraries are that they arise from, and correspond to, accessible regions of cellular chromatin. Throughout the Specification Appellants refer to methods of production of libraries which do not include only inaccessible regions of chromatin and to polynucleotides and libraries corresponding to accessible regions of chromatin. (See *e.g.*, Spec. 4:27-32 and Spec. 27: 13-34.) Thus, we do not agree with the Examiner that on the record before us the term “consisting essentially of” should be construed as equivalent to the term “comprising”.

Nevertheless, claim 66 is drawn to a polynucleotide. The Examiner finds that, because of the method used to make them, the Clontech libraries inherently “comprise clones that either have an insert that consists entirely of polynucleotide sequence from regions of cellular chromatin that are accessible . . . , or have an insert that comprises polynucleotide sequence from the accessible region and sequence from the inaccessible region in the same insert” (Answer 4-5).

Appellants do not dispute this finding. (Appeal Br. 15: “[D]igestion of naked DNA (as described in Clontech) will necessarily result in a collection (library) of DNA fragments that include both accessible and nonaccessible regions.”) Thus, the evidence of record shows that at least one of the polynucleotides of the Clontech libraries will “consist essentially of” accessible regions of chromatin, as claimed. It is of no import that the polynucleotide of accessible regions of chromatin is present in a library

because there is no requirement in claim 66 that the polynucleotide be isolated from other polynucleotides.

Appellants argue that “[b]y no stretch of the imagination could digestion of naked DNA, under any circumstances, possibly produce a library of polynucleotides consisting essentially of accessible regions, as claimed.” (App. Br. 14.) We do not find this argument convincing. Again, claim 66 is drawn to a polynucleotide and not to a library. As indicated herein, Clontech discloses a polynucleotide consisting of accessible regions of chromatin, and therefore it is of no consequence that the library of Clontech also includes polynucleotides comprising a mixture of accessible regions and inaccessible regions and polynucleotides comprising accessible regions of chromatin.

Appellants argue that Clontech does not inherently anticipate claims 66 and 67. (Appeal Br. 15.) Because the libraries of Clontech include polynucleotides consisting essentially of accessible regions of chromatin, Clontech inherently discloses the claimed subject matter. As to the library of claim 67, the claimed library “comprises” polynucleotides of accessible regions of cellular chromatin such as those disclosed in Clontech. The term “comprising” is inclusive and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed. Cir. 1986). Because the Clontech libraries comprise polynucleotides of accessible regions of cellular chromatin, Clontech anticipates the library of claim 67.

The anticipation rejection is affirmed.

SUMMARY

The anticipation rejection is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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